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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,910	01/12/2006	Jonathan Alexander Terrett	2543-1-040PCT/US	1458
23565	7590	11/14/2008		
KLAUBER & JACKSON 411 HACKENSACK AVENUE HACKENSACK, NJ 07601			EXAMINER HOLLERAN, ANNE L	
			ART UNIT	PAPER NUMBER
			1643	
			MAIL DATE	DELIVERY MODE
			11/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/524,910	Applicant(s) TERRETT, JONATHAN ALEXANDER	
	Examiner ANNE L. HOLLERAN	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Applicant's election of Group IV in the reply filed on 8/8/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-32 are cancelled. New claims 33-41 are added.

Claims 33-41 are pending and examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is that the specification fails to describe the genus of "PTK7" polypeptides.

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The specification defines a PTK7 polypeptide as comprising or consisting of SEQ ID NO: 1; or a derivative which retains the activity of PTK7 and has one or more amino acid substitutions, modifications, deletions or insertions relative the amino acid sequence of SEQ ID NO: 1 (see page 3, lines 25-29). The specification does not identify an activity for a polypeptide having the amino acid sequence of SEQ ID NO: 1. The specification does not provide any examples of polypeptides with substitutions, modifications, deletions, or insertions that retains the activity of SEQ ID NO: 1. The prior art teaches that a protein having the sequence of SEQ ID NO: 1 is an inactive kinase (see Jung, J.-W et al., *Biochimica et Biophysica Acta*, 1579: 153-163, 2002). Furthermore, in general the relationship between protein primary structure and protein function is unpredictable. For example, Bowie et al (*Science*, 247: 1306-1310, 1990) teaches that while it is known that many amino acid substitutions are possible in any given protein, the position with the protein sequence where such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Burgess et al (*J. Cell Biology*, 111 : 2129-2138, 1990) teaches that replacement of a single lysine residue at position 118 of acidic fibroblast growth factor by glutamic acid led to the substantial loss of heparin binding, receptor binding and biological activity of the protein. Lazar et al (*Molecular and Cellular Biology*, 8: 1247-1252, 1988) teaches that replacement of aspartic acid at position 47 with alanine or asparagines does not affect biological activity while replacement with serine or glutamic acid sharply reduces the biological activity of the protein. These references demonstrate that even a single amino acid substitution will often dramatically affect the biological activity and characteristics of a protein. Thus, the specification has presented a genus,

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PTK7 polypeptides, and provided one example (that of SEQ ID NO: 1), where no function is defined for that sequence.

Because the relationship between protein sequence and protein function is not a predictable one, and because in the instant case there does not appear to be any functional assay provided by the specification to test possible sequence variants, the specification does not provide an adequate written description of the genus of PTK7 polypeptides. Therefore, the claimed methods which require detection of PTK7 polypeptides is not adequately described.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 33-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Hess-Stumpp (US 6,780,594; Aug. 24, 2004; effective filing date Oct. 26, 2000).

The claims are drawn to methods comprising the step of detecting and/or quantifying in a biological sample obtained from a subject, a PTK7 polypeptide. The intended use of the method is that of screening for and or diagnosis or prognosis of carcinoma in a subject. The level of the PTK7 polypeptide may be compared to a previously determined reference range or control. The step of detecting may comprise contacting the sample with a capture reagent that is specific for a PTK7 polypeptide, and detecting whether binding has occurred between the capture reagent and

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the polypeptide in the sample, where the detection of the binding may be done using a directly or indirectly labeled detection reagent. The capture reagent may be immobilized on a solid phase.

Hess-Stumpp teaches a method of detecting a PTK7 polypeptide in a patient sample (see col. 1, lines 61-67; col. 1, lines 38-50). Hess-Stumpp teaches comparing the level of the measured polypeptide to that of a control sample of an undiseased woman (col. 2, lines 2-4). Hess-Stumpp teaches detection of PTK7 polypeptides using an antibody that binds to PTK7, where the antibody may be used in an ELISA, an RIA, immunohistochemistry, or where the antibody is immobilized onto a vehicle made of glass or silicon (antibody chip) (see column 2, lines 9-33). Hess-Stumpp teaches methods for detection of PTK7 where binding of the antibody to PTK7 is detected using a biotinylated second antibody (see column 5, line 43 – column 6, line 2). Hess-Stumpp also teaches Western blot assays where the detection is done using a second antibody that may be labeled. Hess-Stumpp also teaches a solid-phase immunoassay, where the antibodies are bonded to a polymer carrier matrix, where detection is accomplished by the use of a second antibody that may be labeled with a radioactive or fluorescent label (see column 6, lines 7- 58). Therefore, Hess-Stumpp teaches methods that are the same as that claimed.

Claims 33-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Mack (US 7,189,507; Mar. 13, 2007; effective filing date Apr. 12, 2002).

Mack teaches a method of detection in a biological sample from a patient a polypeptide encoded by the a nucleic acid molecule having a nucleotide sequence as shown in Tables 1-20 (column 4, lines 23-38). Mack discloses the nucleotide sequence SEQ ID NO: 60, which is the same as that of SEQ ID NO: 1 (see alignment included). Mack discloses that one of the

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nucleotide sequences encodes PTK-7 (see Table 2A, columns 107 and 108). Mack discloses methods useful for diagnosing ovarian cancer (col. 6, lines 57-60). Mack discloses methods comprising detecting PTK-7, where expression is compared between normal disease states (col. 20, lines 3-65; col. 40, lines 23-29). Mack discloses use of antibodies in the detection of PTK-7 (col. 40, lines 55-65). Mack discloses detection by the use of a detectably labeled antibody (see column 42, lines 1-2). Mack discloses cancer probes attached to biochips (see col. 42, lines 43-47). Therefore, Mack discloses methods that are the same as that claimed.

The following is an alignment between instant SEQ ID NO: 1 and SEQ ID NO: 60 of Mack:

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US-10-173-999-60
; Sequence 60, Application US/10173999
; Patent No. 7189507
; GENERAL INFORMATION:
; APPLICANT: Mack, David H.
; APPLICANT: Gish, Kurt C.
; APPLICANT: Eos Biotechnology, Inc.
; TITLE OF INVENTION: Methods of Diagnosis of Ovarian Cancer, Compositions
; TITLE OF INVENTION: and Methods of Screening for Modulators of Ovarian
; TITLE OF INVENTION: Cancer
; FILE REFERENCE: 018501-002420US
; CURRENT APPLICATION NUMBER: US/10/173,999
; CURRENT FILING DATE: 2002-06-17
; PRIOR APPLICATION NUMBER: US 60/299,234
; PRIOR FILING DATE: 2001-06-18
; PRIOR APPLICATION NUMBER: US 60/315,287
; PRIOR FILING DATE: 2001-08-27
; PRIOR APPLICATION NUMBER: US 60/350,666
; PRIOR FILING DATE: 2001-11-13
; PRIOR APPLICATION NUMBER: US 60/372,246
; PRIOR FILING DATE: 2001-04-12
; NUMBER OF SEQ ID NOS: 163
; SOFTWARE: PatentIn Ver. 2.1
; SEQ ID NO 60
; LENGTH: 1070
; TYPE: PRT
; ORGANISM: Homo sapiens
US-10-173-999-60

Query Match          100.0%; Score 5656; DB 3; Length 1070;
Best Local Similarity 100.0%; Pred. No. 0;
Matches 1070; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy      1 MGAARGSPARPRRLPLL SVLLLP LLGGTQTAIVFIKQPSSQDALQGRRALLRCEVEAPGP 60
      |||
Db      1 MGAARGSPARPRRLPLL SVLLLP LLGGTQTAIVFIKQPSSQDALQGRRALLRCEVEAPGP 60

Qy      61 VH VYWL LDGAPVQD TERRFAQGSSLSFAAVDRLQDSGTFQC VARD DVTGEEARSANASFN 120
      |||
Db      61 VH VYWL LDGAPVQD TERRFAQGSSLSFAAVDRLQDSGTFQC VARD DVTGEEARSANASFN 120

Qy      121 IKWIEAGPVVLKHPASEABIQPQTQVTLRCHIDGHP RPTYQWFRDGTPLSDGQSNHTVSS 180
      |||
Db      121 IKWIEAGPVVLKHPASEABIQPQTQVTLRCHIDGHP RPTYQWFRDGTPLSDGQSNHTVSS 180

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Qy	181	KERNLTLRPAGPEHSGLYSCCAHSAFGQACSSQNFTLSIADES FARVVLAPQDVVVARYE	240
Db	181	KERNLTLRPAGPEHSGLYSCCAHSAFGQACSSQNFTLSIADES FARVVLAPQDVVVARYE	240
Qy	241	EAMFHCQFSAQPPPSLQWLFEDETPITNRSRPPHLRRATVFANGSLLLTQVRPRNAGIYR	300
Db	241	EAMFHCQFSAQPPPSLQWLFEDETPITNRSRPPHLRRATVFANGSLLLTQVRPRNAGIYR	300
Qy	301	CIGQGQRGPPIILEATLHLAEIEDMPLFEPRVFTAGSEERVTCCLPPKGLPEPSVWWEHAG	360
Db	301	CIGQGQRGPPIILEATLHLAEIEDMPLFEPRVFTAGSEERVTCCLPPKGLPEPSVWWEHAG	360
Qy	361	VRLPTHGRVYQKGHELVLANIAESDAGVYTCHAAANLAGQRRQDVNITVATVPSWLKKPQD	420
Db	361	VRLPTHGRVYQKGHELVLANIAESDAGVYTCHAAANLAGQRRQDVNITVATVPSWLKKPQD	420
Qy	421	SQLEEGKPGYLDCLTQATPKPTVVWYRNQMLISEDSEFEVFKNGTLRINSVEVDGTWYR	480
Db	421	SQLEEGKPGYLDCLTQATPKPTVVWYRNQMLISEDSEFEVFKNGTLRINSVEVDGTWYR	480
Qy	481	CMSSTPAGSIEAARVQVLEKLFKFTPPPQQCMEFDKEATVPCSATGREKPTIKWERAD	540
Db	481	CMSSTPAGSIEAARVQVLEKLFKFTPPPQQCMEFDKEATVPCSATGREKPTIKWERAD	540
Qy	541	GSSLPEWVTDNAGTLHFARVTRDDAGNYTCIASNGPQGGIRAHVQLTVAVFITFKVEPER	600
Db	541	GSSLPEWVTDNAGTLHFARVTRDDAGNYTCIASNGPQGGIRAHVQLTVAVFITFKVEPER	600
Qy	601	TTVYQGHTALLQCEAQGDPKPLIQWKGKDRILDPTKLGPRMHIFQNGSLVIHDVAPEDSG	660
Db	601	TTVYQGHTALLQCEAQGDPKPLIQWKGKDRILDPTKLGPRMHIFQNGSLVIHDVAPEDSG	660
Qy	661	RYTCIAGNSCNIKHTEAPLYVVDKPVPEESEGPGSPPPYKMIQTIGLSVGAAYYIIAIVL	720
Db	661	RYTCIAGNSCNIKHTEAPLYVVDKPVPEESEGPGSPPPYKMIQTIGLSVGAAYYIIAIVL	720
Qy	721	GLMFYCKKRCKAKRLQKQPEGEEPEMECLNGGPLQNGQPSAEIQEEVALTSLGSGPAATN	780
Db	721	GLMFYCKKRCKAKRLQKQPEGEEPEMECLNGGPLQNGQPSAEIQEEVALTSLGSGPAATN	780
Qy	781	KRHSTSDKMHFPRSSLQPIITTLGKSEFGEVFLAKAQGLEEGVAETLVLVKSLQTKDEQQQ	840
Db	781	KRHSTSDKMHFPRSSLQPIITTLGKSEFGEVFLAKAQGLEEGVAETLVLVKSLQTKDEQQQ	840
Qy	841	LDFRRELEMFGLNHNANVRLGLCREAEPHYMVLEYVDLGDLDKQFLRISKSKDEKLKSQ	900
Db	841	LDFRRELEMFGLNHNANVRLGLCREAEPHYMVLEYVDLGDLDKQFLRISKSKDEKLKSQ	900
Qy	901	PLSTKQKVALCTQVALGMEHLSNNRFVHKDLAARNCLVSAQRQVKVSALGLSKDVYNSEY	960
Db	901	PLSTKQKVALCTQVALGMEHLSNNRFVHKDLAARNCLVSAQRQVKVSALGLSKDVYNSEY	960
Qy	961	YHFRQAWVPLRWMSPEAILEGDFSTKSDVWAFGLMWVFTTHGEMPHGGQADDEVLADLQ	1020
Db	961	YHFRQAWVPLRWMSPEAILEGDFSTKSDVWAFGLMWVFTTHGEMPHGGQADDEVLADLQ	1020
Qy	1021	AGKARLPQPEGCPKLYRLMQRCWALSPKDRPSFSEIASALGDS TVDSKP	1070
Db	1021	AGKARLPQPEGCPKLYRLMQRCWALSPKDRPSFSEIASALGDS TVDSKP	1070

Conclusion

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
November 10, 2008
/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643